

No. 14-15385

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

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**FLOYD LUMAN *et al.*,**  
*Plaintiffs and Appellants,*

vs.

**NAC MARKETING COMPANY, LLC *et al.*,**  
*Defendants and Appellees*

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On Appeal From a Judgment  
of the United States District Court, Eastern District of California  
No. C13-00656-KJM-AC, The Honorable Kimberly J. Mueller

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**BRIEF OF APPELLEE NAC MARKETING COMPANY, LLC**

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## CORPORATE DISCLOSURE STATEMENT

(F.R.A.P. 26.1(a))

The following information is provided pursuant to Federal Rule of Appellate Procedure 26.1 for appellee NAC Marketing Company, LLC:

NAC Marketing Company, LLC is a wholly owned subsidiary of New Vitality Transaction Holdings, Inc. New Vitality Transaction Holdings, Inc. is a wholly owned subsidiary of New Vitality Holdings, LLC, a privately held company. No publicly held corporation owns more than 10 percent of NAC Marketing Company, LLC's stock.



## I. INTRODUCTION

It is ironic that a false advertising class action would rest on a demonstrably false allegation. Appellants alleged that defendant NAC Marketing Company, LLC falsely advertised that Super Beta Prostate was effective in treating a condition called benign prostate hyperplasia (“BPH”). The foundation for Appellants’ claim was a scientific study published in *The Lancet*, a respected British medical journal. Appellants’ complaint specifically and selectively quoted *The Lancet* study, arguing that it demonstrated that the active ingredient in Super Beta Prostate, beta-sitosterol, was not effective for treating BPH. *The Lancet* study actually reached the opposite conclusion: “Significant improvement in symptoms and urinary flow parameters show *the effectiveness of beta-sitosterol in the treatment of benign prostatic hyperplasia.*”<sup>1</sup> In other words, the active ingredient in Super Beta Prostate works.

The district court refused to rely on Appellants’ description of *The Lancet* study and ordered Appellants to file a copy of the study prior to the hearing on the motion to dismiss. *The Lancet* study was in the record, but Appellants omit it from their Excerpts of Record, even

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<sup>1</sup> Supplemental Excerpts of Record (“SER”) at 16 (emphasis added).

though their Opening Brief continues to tout it as evidence of false advertising. Simply put, *The Lancet* study conclusively shows that Appellants' entire case lacks factual or legal merit.

Given this context, the district court had numerous options that supported dismissing this case with prejudice. The court chose to dismiss on the threshold jurisdictional basis of lack of standing. The first named plaintiff suffered no injury and lacked standing because he received a full refund of all money paid to NAC. The second named plaintiff created a supposed "injury" simply for the purpose of suing. His belligerent phone calls to NAC *before he even ordered the product* – recordings of which were in the district court record but that Appellants also omitted from their Excerpts of Record – demonstrate that he was not a sincere customer. Days after receiving a free trial shipment of Super Beta Prostate, he joined the case as a second putative class representative in the amended complaint. But his claim was mooted when NAC refunded the \$6.99 he paid for shipping his free sample. The district court's decisions in this regard were inarguably correct.

On appeal, Appellants rely on three inapposite cases that do not establish either Appellant had standing. *Kagan v. Gibraltar Sav. &*

*Loan Ass'n*, 35 Cal. 3d 582 (1984), a California Supreme Court case, says nothing about Article III federal court standing, and its central premise – that a plaintiff who suffers no monetary injury can sue under California’s Consumer Legal Remedies Act (“CLRA”) – has been overruled. *See Meyer v. Sprint Spectrum L.P.*, 45 Cal. 4th 634 (2009).

Appellants also rely on two decisions from this Court, *Pitts v. Terrible Herbst, Inc.*, 653 F.3d 1081 (9th Cir. 2011), and *Diaz v. First Am. Home Buyers Protection Corp.*, 732 F.3d 948 (9th Cir. 2013). Neither of these cases can create standing here, as both involve the unique procedural posture of cases where plaintiffs did not accept defendants’ Rule 68 offers of judgment, rendering those offers “legal nullit[ies].” *Diaz*, 732 F.3d at 954 (quoting *Genesis Healthcare Corp. v. Szymczyk*, 133 S. Ct. 1523, 1533-34 (2013) (Kagan, J., dissenting)). No Rule 68 offer was made or rejected here. NAC simply refunded Appellants’ money once they complained that the product did not work. Appellants’ claimed disinterest in getting their money back cannot create federal jurisdiction where none otherwise exists.<sup>2</sup>

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<sup>2</sup> *See Epstein v. JPMorgan Chase & Co.*, No. 13 Civ. 4744 (KPF), 2014 WL 1133567, at \*7 (S.D.N.Y. March 21, 2014); *Brandon v. National R.R. Passenger Corp. Amtrak*, No. CV 12-5796 PSG

The district court also correctly concluded that it lacked jurisdiction to decide Appellants' claims for injunctive relief. As both Appellants made clear that they did not believe the product worked, there is no reasonable likelihood they will ever buy it, or suffer any alleged harm, again. Federal courts lack jurisdiction to grant injunctions in such cases.<sup>3</sup> The district court's dismissal on jurisdictional grounds should be affirmed.

But even if this Court were to conclude that the district court had jurisdiction over this case, the dismissal with prejudice should be affirmed. As noted, *The Lancet* study demonstrates that Super Beta Prostate's primary active ingredient is effective in treating BPH. So any allegation to the contrary is demonstrably false and cannot support a claim for false advertising. Appellants' other random allegations of falsity merely establish, at most, that NAC lacked scientific substantiation to support its advertising claims – notwithstanding the contrary conclusions of *The Lancet* study. A

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(VBKx), 2013 WL 800265, at \*4-\*5 (C.D. Cal. March 1, 2013).

<sup>3</sup> See, e.g., *Delarosa v. Boiron, Inc.*, No. SACV 10-1569-JST (CWx), 2012 WL 8716658 (C.D. Cal. Dec. 28, 2012); *Burns v. Tristar Prods., Inc.*, No. 14-cv-749-BAS (DHB), 2014 WL 3728115, at \*3 (S.D. Cal. July 25, 2014); *Mason v. Nature's Innovation, Inc.*, No. 12cv3019 BTM (DHB), 2013 WL 1969957, at \*2 (S.D. Cal. May 13, 2013); *Rahman v. Mott's LLP*, No. CV 13-3482 SI, 2014 WL 325241, at \*10 (N.D. Cal. Jan. 29, 2014).

claim that a defendant lacks substantiation for advertising claims, which underlies every one of the counts alleged, is not actionable under California law. *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal. App. 4th 1336, 1344 (2003). For that reason as well, the dismissal may be affirmed.

## **II. STATEMENT OF THE CASE**

### **A. NAC's Advertising of Super Beta Prostate.**

NAC markets a dietary supplement called “Super Beta Prostate” through television and radio commercials and on certain websites it maintains, including [www.newvitality.com](http://www.newvitality.com) and [www.betaprostate.com](http://www.betaprostate.com). (ER 175 ¶ 9; SER 45 ¶ 3.)<sup>4</sup> None of NAC's advertisements for Super Beta Prostate has ever referred to or used the terms “benign prostate hyperplasia” or “BPH.” (SER 45 ¶ 4.)

### **B. Appellant Luman.**

Appellant Luman alleged that he purchased Super Beta Prostate after allegedly “review[ing] the product's labeling and watch[ing] the advertisement with [celebrity endorser] Joe Theismann” and allegedly

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<sup>4</sup> Courts may consider evidence outside the complaint in ruling on a challenge to subject matter jurisdiction under Rule 12(b)(1). *Savage v. Glendale Union High Sch., Dist. No. 205, Maricopa Cnty.*, 343 F.3d 1036, 1051 n.2 (9th Cir. 2003), *cert. denied*, 541 U.S. 1009 (2004); *Wood v. City of San Diego*, 678 F.3d 1075, 1083 n.8 (9th Cir. 2012).

relying on certain claims that the product “would treat the symptoms of benign prostate hyperplasia.” (ER 174 ¶ 7.) Luman ordered a no-risk sample of Super Beta Prostate on September 4, 2012, and was charged only shipping and handling. He was enrolled in the automatic shipment plan, and was sent and charged for four additional shipments between October 3, 2012 and December 30, 2012. On January 10, 2013, he called NAC to cancel his order. (ER 141 ¶¶ 4-6.)

On January 21, 2013, through his counsel, Luman sent NAC a demand letter accusing NAC of making false and misleading representations about Super Beta Prostate and demanding “full restitution.” (ER 109-11; ER 197 ¶ 106.)

On February 11, 2013, NAC issued a full refund to Luman for the purchase price and shipping costs of all of his orders. (ER 141 ¶ 7.)

Luman filed this lawsuit against NAC and Joe Theismann on April 4, 2013. (ER 203.) Luman’s original complaint cited *The Lancet* study as the basis for the alleged falsity of NAC’s ads. (ER 204 ¶ 1.)

On April 26, 2013, NAC moved to dismiss, arguing, among other things, that Luman lacked standing to sue because he had no

injury that could be redressed by this litigation. (Dkt. No. 6.) Rather than oppose this motion, on May 10, 2013 Luman filed a First Amended Complaint (“FAC”), which added Amkraut as an additional plaintiff. (ER 170.) The only other substantive change to the FAC was to delete several references to NAC’s allegedly “unsubstantiated” claims, presumably attempting to circumvent NAC’s argument that a lack of substantiation theory is not actionable. *Compare* ER 222-23 ¶¶ 60-61 *with* ER 191-92 ¶¶ 62-63; *see also infra* Part V.

**C. Appellant Amkraut.**

When this lawsuit was first filed on April 4, 2013, Amkraut had never purchased Super Beta Prostate.

Between April 10 and April 12, 2013, Amkraut called NAC three times to discuss Super Beta Prostate. On each occasion, he was angry, hostile, and belligerent, swearing at the customer service representatives, and interrupting and berating them as they attempted to go through their sales script. (ER 137-38 ¶¶ 5-8; SER 22 (Exs. A-C).) Recordings of Amkraut’s verbally abusive telephone calls were before the district court and are before this Court.<sup>5</sup> Amkraut was not a

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<sup>5</sup> The recordings of Amkraut’s second and third calls (Exhibits B and C) are lengthy because he was placed on hold for a time. Amkraut’s attitude toward and verbal abuse of NAC’s customer service

sincere customer simply ordering the product in good faith – it is unmistakable that he was attempting to gin up his own lawsuit.

Despite his expressed rage with NAC customer representatives, on April 12, 2013 Amkraut nonetheless ordered a *free* no-risk sample of Super Beta Prostate, for which he was charged only shipping and handling. (ER 138 ¶ 8; SER 22 (Ex. C).) His shipment was delivered to him on April 23, 2013. (ER 142 ¶¶ 8-10.) It is not clear from the complaint when Amkraut took Super Beta Prostate or how long he continued to use the product (if in fact he did use it).

As noted, on May 10, 2013, less than three weeks after receiving his free trial shipment, Amkraut became a plaintiff in this action. On that same date, through his counsel, he sent NAC a CLRA demand letter that was virtually identical to Luman's. (ER 197 ¶ 107.)

On May 13, 2013, NAC issued a refund to Amkraut of his shipping and handling charge, which was the only money charged for his trial shipment of Super Beta Prostate. (ER 142 ¶ 11.)

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representatives and supervisors are most clearly expressed in Exhibit B, after the 10-minute mark.



**D. The FAC.**

The FAC asserted claims under various legal theories, all based on the central contention that the ads for Super Beta Prostate misrepresented its effectiveness in treating BPH. *See generally* ER 170-99. Appellants sought to represent a class of “all persons in the United States who purchased Super Beta Prostate, excluding those that made such purchase for the purpose of resale” and a subclass of California purchasers. (ER 191 ¶¶ 59-60.)

Appellants alleged that NAC’s advertising makes *implied* claims that Super Beta Prostate will treat and cure BPH, because it represents that it will treat various symptoms that Appellants associate with BPH. (ER 171 ¶ 1; ER 173 ¶ 3; ER 179-83 ¶¶ 26-32; ER 185-87 ¶¶ 39-43; ER 188-91 ¶¶ 46, 48-51, 53, 57; *see also* ER 184 ¶ 34 (alleging that “Defendants do not expressly refer to BPH, but instead discuss the symptoms of an ‘aging prostate,’ . . . [which] are the *exact symptoms* of BPH”) (emphasis in original); ER 185 ¶ 39 (alleging that ads with Joe Theismann that Appellants allegedly saw do not “directly refer[] to BPH”); ER 190 ¶ 53 (describing label as not mentioning BPH); SER 9:12-10:9 (Appellants’ counsel confirming that the ads did not mention BPH).)

The FAC, quoting from a portion of *The Lancet* study, alleged that “compounds [including beta-sitosterol] are no longer considered suitable for the treatment of BPH. Indeed, in 1995, a researcher studying Harzol® wrote:

The effect of phytopharmaceuticals on BPH is controversial because no clear mechanisms of action have been established, and their effect has been attributed to placebo responses. . . . Since other forms of medical treatment of BPH have been shown to be effective, it is questionable whether phytopharmaceutical drugs should continue to be prescribed.”

(ER 171 ¶ 1.) As discussed below, *The Lancet* study actually concluded that beta-sitosterol was effective in treating BPH. The portion of *The Lancet* study quoted in the FAC was a discussion of why there was a need to study beta-sitosterol. The study resolved the “controversy” about beta-sitosterol by concluding that it is effective in treating BPH. (SER 5:21-6:13.)

#### **E. The Dismissal of the Complaint.**

On May 28, 2013, NAC moved to dismiss the FAC for lack of subject matter jurisdiction under Rule 12(b)(1), the doctrine of primary jurisdiction, and for failure to state a claim under Rule

12(b)(6).<sup>6</sup> (ER 143.) Appellants filed an opposition on June 14, 2013 (ER 56) and NAC replied on June 21, 2013 (ER 41).

On July 9, 2013, the district court sua sponte ordered Appellants to file a copy of *The Lancet* study they cited and relied on in the FAC and their opposition to the motion to dismiss as a primary basis for their claims of falsity. (Dkt. No. 30.)

Appellants submitted the study on July 15, 2013.<sup>7</sup> (SER 13.) Among other things, the study explains that “[s]ignificant improvement in symptoms and urinary flow parameters show the effectiveness of beta-sitosterol in the treatment of benign prostatic hyperplasia” and “[t]he results [of the study] show a significant effect of beta-sitosterol in patients with symptomatic BPH on symptoms . . . Objective parameters of urine flow were also improved more than in the placebo group.” (SER 16, 19.)

The court heard argument on the motions to dismiss on August 2, 2013. (Dkt. No. 36; *see generally* Reporters’ Transcript.) On August 8, 2013, the court ordered the parties to submit supplemental briefs addressing the impact on standing of the U.S. Supreme Court’s

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<sup>6</sup> Joe Theismann also moved to dismiss the FAC. (ER 112.)

<sup>7</sup> Appellants did not include this submission in the Excerpts of Record submitted to this Court. NAC has included it as Exhibit 3 to its Supplemental Excerpts of Record.

recent decision in *Genesis Healthcare Corp. v. Szmczyk*, 133 S. Ct. 1523 (2013). (Dkt. No. 37.) The parties submitted this briefing on August 16, 2013. (Dkt. Nos. 39, 40.) On September 11, 2013, Appellants filed a request for judicial notice of an FDA regulation issued in 1990 (ER 21); NAC responded on September 13. (SER 1.) The court issued an order granting the motion on the ground of lack of standing on February 4, 2014 (ER 8), and entered judgment in favor of NAC and Theismann. (ER 7.)

### **III. SUMMARY OF ARGUMENT**

The district court's order of dismissal should be affirmed. The court lacked jurisdiction to adjudicate Luman's individual and class claims for monetary or injunctive relief because NAC had fully satisfied his claim prior to the filing of the action, and he was not likely to buy the product in the future. The court also lacked jurisdiction to adjudicate Amkraut's claims, which became moot when NAC fully satisfied his claim, and he was not likely to buy the product in the future.

The district court's order of dismissal also may be affirmed on the alternative ground that Appellants failed to state a claim because *The Lancet* study negates their claim that NAC's ads were false, and

their case otherwise relies on a non-actionable lack-of-substantiation theory.<sup>8</sup>

#### **IV. THE ACTION WAS PROPERLY DISMISSED UNDER RULE 12(B)(1) BECAUSE THE DISTRICT COURT LACKED SUBJECT MATTER JURISDICTION**

The district court found that it lacked jurisdiction over Appellants' claims, individually and on behalf of a putative class, because they lacked standing and their claims were moot. This decision was correct, as both Appellants had been made whole and could not pursue claims for monetary or injunctive relief on behalf of themselves or a class.

##### **A. Federal Standing and Mootness.**

A litigant invoking the jurisdiction of a federal court must have “standing” to do so, which requires that he “must have suffered, or be threatened with, an actual injury traceable to the defendant and likely to be redressed by a favorable judicial decision.” *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477 (1990). “In order to invoke federal-court jurisdiction, a plaintiff must demonstrate that he possesses a

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<sup>8</sup> If this Court concludes that the district court did have standing, the Court may affirm the dismissal on this alternative ground. *See Morrison v. National Australia Bank Ltd.*, 561 U.S. 247, 254 (2010); *Wood*, 678 F.3d at 1084-85, 1086; *Bell v. Health-Mor, Inc.*, 549 F.2d 342, 345 (5th Cir. 1977).

legally cognizable interest, or personal stake, in the outcome of the action. This requirement ensures that the Federal Judiciary confines itself to the constitutionally limited role of adjudicating actual and concrete disputes, the resolutions of which have direct consequences on the parties involved.” *Genesis Healthcare*, 133 S.Ct. at 1528 (citations and internal quotation marks omitted).

“‘[W]hen subject matter jurisdiction is challenged under Federal Rule of Procedure 12(b)(1), the plaintiff has the burden of proving jurisdiction in order to survive the motion.’” *Kingman Reef Atoll Investments, L.L.C. v. United States*, 541 F.3d 1189, 1197 (9th Cir. 2008) (citation omitted). A federal court must dismiss an action upon determining that it lacks subject matter jurisdiction. Fed. R. Civ. P. 12(h)(3). In ruling on a Rule 12(b)(1) motion, the district court may consider evidence outside of the pleadings. *See Savage*, 343 F.3d at 1051 n.2.

Even if a plaintiff had standing at the time the federal complaint was filed, a federal court lacks subject matter jurisdiction to hear a claim that becomes moot during the pendency of the litigation. *Foster v. Carson*, 347 F.3d 742, 745 (9th Cir. 2003). “‘Mootness can be characterized as the doctrine of standing set in a time frame: The

requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” *Id.* (internal citation omitted). “If an intervening circumstance deprives the plaintiff of a ‘personal stake in the outcome of the lawsuit,’ at any point during litigation, the action can no longer proceed and must be dismissed as moot.” *Genesis Healthcare*, 133 S. Ct. at 1528; *Pitts*, 653 F.3d at 1086 (“Whether ‘the dispute between the parties was very much alive when the suit was filed . . . cannot substitute for the actual case or controversy that an exercise of this [c]ourt’s jurisdiction requires’”) (quoting *Honig v. Doe*, 484 U.S. 305, 317 (1988)).

In federal court, if a plaintiff lacks Article III standing, standing cannot be grounded on a statute that purports to grant a right to sue. “It is settled that Congress cannot erase Article III’s standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing.” *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997); *see also Cetacean Community v. Bush*, 386 F.3d 1169, 1174-75 (9th Cir. 2004) (“If a plaintiff lacks Article III standing, Congress may not confer standing on that plaintiff by statute.”).

**B. Luman Lacked Standing to Pursue Monetary Relief Because His Payments Were Refunded Before He Filed Suit.**

As a matter of law, Luman has always lacked standing because when he filed the lawsuit he had no injury that could be redressed in federal court. As discussed above, NAC refunded Luman's purchase price and shipping charges in full nearly two months before he filed his lawsuit. As he had no standing to bring his individual claims, he also could not pursue claims on behalf of a class. *See O'Shea v. Littleton*, 414 U.S. 488, 494 (1974) ("if none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class").

Luman's argument on appeal is based on a single case, *Kagan v. Gibraltar Sav. & Loan Ass'n*, 35 Cal. 3d 582 (1984), *disapproved in part by Meyer v. Sprint Spectrum L.P.*, 45 Cal. 4th 634 (2009). (AOB 15-19). Luman did not even mention the 30-year-old *Kagan* decision in the district court. Yet according to Luman, *Kagan* dictates the result in his case and requires a finding that he had standing. Thus, under Luman's own argument, if *Kagan* cannot provide a basis for jurisdiction, the district court's judgment must be affirmed.



But there is a glaring, dispositive reason why *Kagan* does not provide Luman with standing: *Kagan* is a state-court decision. Unlike federal courts, state courts need not concern themselves with Article III standing concepts of actual injury, causation, or redressability. And unlike in federal courts, standing in state court can be created by a statute that may not require an actual injury. *Cantrell v. City of Long Beach*, 241 F.3d 674, 683 (9th Cir. 2001) (“although the birdwatchers may well have standing under California [statute] to bring their suit in state court, that does not help them here. A party seeking to commence suit in federal court must meet the stricter federal standing requirements of Article III.”). If, as *Kagan* held, a plaintiff may sue in state court under the CLRA even without suffering monetary damage, that is irrelevant to whether that same plaintiff can bring that same claim in federal court. *See Epstein*, 2014 WL 1133567, at \*10 (rejecting plaintiff’s reliance on *Kagan* to pursue class CLRA claims: “Plaintiff may not use a California statute to expand the scope of standing afforded under Article III”).

There is also a separate reason why *Kagan* cannot accord standing to Luman here. In *Kagan*, the Court interpreted the CLRA’s requirement that a plaintiff must have suffered “any damage” as a

result of the defendant's alleged wrongful act to include plaintiffs who merely were exposed to an allegedly unlawful practice, regardless of whether they actually experienced a monetary injury:<sup>9</sup>

We . . . reject [defendant's] effort to equate pecuniary loss with the standing requirement [of the CLRA] that a consumer "suffer[] any damage." As it is unlawful to engage in any of the deceptive business practices enumerated in section 1770, consumers have a corresponding legal right not to be subjected thereto. Accordingly, we interpret broadly the requirement of section 1780 that a consumer "suffer[] any damage" to include the infringement of any legal right as defined by section 1770.

*Id.* at 593. In other words, central to *Kagan*'s holding that the plaintiff, who had suffered no financial injury, could pursue her CLRA claims and those of the class was the predicate assumption that a plaintiff with no pecuniary loss could still have suffered "damage" under the CLRA merely by being exposed to the challenged business practices.<sup>10</sup>

That key aspect of *Kagan* is no longer good law. In *Meyer*, the California Supreme Court "disapprove[d]" this part of *Kagan*. *Meyer*,

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<sup>9</sup> The CLRA states that "[a]ny consumer who suffers any damage as a result of the use or employment by any person of a method, act, or practice declared to be unlawful by Section 1770 may bring an action against that person . . . ." Cal. Civ. Code § 1780(a).

<sup>10</sup> The Court noted that on remand, the trial court could consider issues of the plaintiff's typicality and adequacy, given that she had no financial stake in the matter. *Id.* at 595-96.

45 Cal. 4th at 642-43 & n.3. The Court rejected the notion expressed in *Kagan* that mere exposure to a business practice was sufficient to create CLRA “damage.” “[T]he statute provides that in order to bring a CLRA action, not only must a consumer be exposed to an unlawful practice, but some kind of damage must result.” *Id.* at 641-43. The *Meyer* Court held that the CLRA’s standing requirement that a plaintiff have suffered “damage” requires *monetary* damage.

Applying the holding and reasoning of *Meyer* to the facts of *Kagan*, the plaintiff in *Kagan* had no “damage” within the meaning of the CLRA. And applying the holding and reasoning of *Meyer* to Luman’s case, the fact that he had no monetary injury when he filed the suit means that he lacked standing.<sup>11</sup>

**C. Amkraut’s Claim for Monetary Relief Was Mooted  
When His Payment Was Refunded.**

Amkraut presents a slightly different issue. As noted, the tenor and timing of Amkraut’s phone calls to NAC make it appear likely that Amkraut only purchased Super Beta Prostate in order to pursue litigation, which is insufficient to confer standing. *See Saulic v.*

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<sup>11</sup> Luman asserts that *Meyer*’s disapproval of *Kagan* does not impact his case because he “alleges that he incurred actual damages in the amount of his purchase price and shipping and handling charges.” (AOB 18 n.3.) He may *allege* this, but he ignores the key point that NAC had refunded this money prior to the filing of the suit.

*Symantec Corp.*, 596 F. Supp. 2d 1323, 1329 (C.D. Cal. 2009) (citing *Buckland v. Threshold Enters., Ltd.*, 155 Cal. App. 4th 798, 815 (2007), *disapproved on other grounds*, *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310 (2011)). It was appropriate for the district court to consider the recordings of these phone calls when determining whether Amkraut had standing to assert a claim in federal court, and they clearly impacted the court's decision concerning whether Amkraut had suffered an injury that would give him standing.

In addition, Amkraut's claims became moot when NAC repaid in full the only money he paid to NAC – the shipping charges associated with his free trial. Amkraut therefore cannot pursue individual or class claims. The district court correctly dismissed this claim as well.

Amkraut relies on only two cases. *See* AOB 20-27 (citing *Pitts*, 653 F.3d 1081, and *Diaz*, 732 F.3d 948).<sup>12</sup> Neither case provides Amkraut with standing.

In *Pitts*, a plaintiff sought to represent a class of employees in wage and hour litigation. Prior to class certification, the defendant

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<sup>12</sup> *Diaz* was decided after briefing and argument on NAC's motion.

made him a Rule 68 offer in an amount exceeding his personal claim. The plaintiff rejected the offer. The defendant then argued that the case had become moot because the offer would have fully compensated the plaintiff, and the court therefore lacked jurisdiction.

This Court held that the fact that the plaintiff's individual claim had become moot did not impact the class claims where the court had not yet ruled on a certification motion. *See Pitts*, 653 F.3d at 1090 (“even if the district court has not yet addressed the class certification issue, mooting the putative class representative's claims will not necessarily moot the class action”).

The *Pitts* Court explained that in such circumstances, the claims were transitory, in that the proposed class representative's claims could expire before review, while the interests of class members would continue or repeat. *Id.* at 1090. The Court held that in order to ensure that the claims of the class members could be litigated despite the mootness of the named plaintiff's claim through a Rule 68 offer, a court may apply the relation-back doctrine, so that if a class is later certified, the certification will relate back to the date of filing the complaint and the class can pursue its claims. The Court recognized that plaintiffs' claims that were mooted mid-litigation by the

defendant's Rule 68 offer of judgment were not "inherently transitory" by their nature, but held:

Where, as here, a defendant seeks to "buy off" the small individual claims of the named plaintiffs, the analogous claims of the class – though not *inherently* transitory – become no less transitory than inherently transitory claims. Thus, although Pitts's claims "are not 'inherently transitory' as a result of being time sensitive, they are 'acutely susceptible to mootness' in light of [the defendant's] tactic of 'picking off' lead plaintiffs with a Rule 68 offer to avoid a class action." The end result is the same: a claim transitory by its very nature and one transitory by virtue of the defendant's litigation strategy share the reality that both claims would evade review.

*Pitts*, 653 F.3d at 1091 (citation omitted; emphasis in original). The Court held that "an unaccepted Rule 68 offer of judgment – for the full amount of the named plaintiff's individual claim and made before the named plaintiff files a motion for class certification – does not moot a class action." *Id.* at 1091-92.

In *Diaz*, 732 F.3d 948, after the district court denied class certification, the defendant made a full Rule 68 offer to the plaintiff. She did not accept it. *Id.* at 950. The district court then granted the defendants' motion to dismiss for lack of jurisdiction, holding that the plaintiff's claims were moot. *Id.* at 951.

This Court held that the unaccepted Rule 68 offer did not render the plaintiff's claims moot because an unaccepted Rule 68 offer is a

legal nullity. The Court relied upon and adopted Justice Kagan's dissent in *Genesis Healthcare*, 133 S. Ct. 1523. Quoting the dissent, this Court stated:

“[A] case becomes moot only when it is impossible for a court to grant any effectual relief whatever to the prevailing party.” By those measures, an unaccepted offer of judgment cannot moot a case. When a plaintiff rejects such an offer – however good the terms – her interest in the lawsuit remains just what it was before. And so too does the court's ability to grant her relief. An unaccepted settlement offer – like any unaccepted contract offer – is a legal nullity, with no operative effect.

*Diaz*, 732 F.3d at 954 (quoting *Genesis Healthcare*, 133 S. Ct. at 1533-34 (Kagan, J., dissenting) (citations omitted)).

Amkraut argues that under *Pitts* and *Diaz*, NAC's refund could not moot his individual or class claims and deprive the district court of jurisdiction. He is wrong.

First, both *Pitts* and *Diaz* arose in the specific context of a Rule 68 offer that was affirmatively rejected or not accepted by the plaintiff. A rejected Rule 68 offer is a *legal nullity*, of no legal effect, and leaves the status quo unchanged, as if the offer never had been made. See *Genesis Healthcare*, 133 S. Ct. at 1533-34 (Kagan, J., dissenting); *Diaz*, 732 F.3d at 954. Thus, a plaintiff who had suffered

an injury before the offer was made still suffers the same injury after the offer has been made and rejected. *Id.*

Here, NAC did not make, and Amkraut did not reject, a Rule 68 offer. Amkraut has *actually received* the very money that he demands in this lawsuit. This payment is not a “legal nullity.” *See Brandon*, 2013 WL 800265, at \*4-\*5 (where defendant tendered to plaintiff a check in the full amount she sought, her claim was moot even though she refused to cash the check; finding *Pitts* inapplicable because it involved a Rule 68 offer).

Amkraut tries to manufacture a legally meaningful distinction by characterizing NAC’s refund as “involuntary,” but this is an irrelevant distinction, as the district court found. (ER 16:17-17:3.) As one court recently explained in similar circumstances:

That Plaintiff received the Refund Check demonstrates the absence of any “actual” injury on which Plaintiff’s standing could be established. . . . The Court cannot accept Plaintiff’s contention that by neither requesting nor cashing the Refund Check, he has somehow created standing. To do so would not only render hollow the injury-in-fact requirement, but would also engender a disincentive among potential litigants to attempt legitimately to resolve disputes without judicial intervention.

*Epstein*, 2014 WL 1133567, at \*7; *see also Brandon*, 2013 WL 800265, at \*4-\*5 (“[a] plaintiff cannot revive a moot claim simply by



refusing tender”). Once the payment was made, Amkraut had no injury that could be redressed by a favorable decision. The money he alleges he wrongfully paid is now in his possession.

Further, *Pitts*’ holding that class claims were not mooted by the mooted of the named plaintiff’s claim depended on the Court’s conclusion that class claims in such cases are transitory and likely to evade review, and thus may be saved from mootness by application of the relation-back doctrine. This holding is of questionable continuing validity. In *Genesis Healthcare*, the U.S. Supreme Court considered an argument that claims that are the subject of an FLSA collective action are transitory and entitled to rely on the relation-back doctrine if the named plaintiff’s claims become moot by the defendant’s Rule 68 offer.<sup>13</sup> The Supreme Court rejected that argument, explaining:

Our cases invoking the “inherently transitory” relation-back rationale do not apply. The “inherently transitory” rationale was developed to address circumstances in which the challenged conduct was effectively unreviewable, because no plaintiff possessed a personal stake in the suit long enough for litigation to run its

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<sup>13</sup> In *Genesis Healthcare*, the Supreme Court held that the mooted of the plaintiff’s individual claim in an FLSA collective action mooted the entire suit. The Court expressly declined to decide the question of whether the unaccepted Rule 68 offer mooted the plaintiff’s claim, and instead simply assumed that it did so and went on to decide the impact of that mootness on the remainder of the action. *Genesis Healthcare*, 133 S. Ct. at 1528-29.

course. . . . **But this doctrine has invariably focused on the fleeting nature of the challenged conduct giving rise to the claim, not on the defendant's litigation strategy.**

. . . Unlike claims for injunctive relief challenging ongoing conduct, a claim for damages cannot evade review; it remains live until it is settled, judicially resolved, or barred by a statute of limitations. Nor can a defendant's attempt to obtain settlement insulate such a claim from review, for a full settlement offer addresses plaintiff's alleged harm by making the plaintiff whole. While settlement may have the collateral effect of foreclosing unjoined claimants from having their rights vindicated in *respondent's* suit, such putative plaintiffs remain free to vindicate their rights in their own suits. They are no less able to have their claims settled or adjudicated following respondent's suit than if her suit had never been filed at all.

*Genesis*, 133 S. Ct. at 1531 (italics in original; bold added).<sup>14</sup>

Under this reasoning, the central concept underlying the decision in *Pitts* cannot survive. That is why numerous courts have questioned the continuing viability of *Pitts* in light of *Genesis*

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<sup>14</sup> The Court made clear that its holding was based on the nature of a collective action, which it repeatedly distinguished from Rule 23 class actions, in part on the basis that a certified class becomes an entity unto itself rather than a collection of individual claims. Some courts have found *Genesis Healthcare's* primary holding irrelevant in the class action context for this reason. But its reasoning regarding whether claims are transitory, based on the Court's own prior cases discussing the notion of transitory claims in the class action context, holds true for class actions as well as collective actions.

*Healthcare*.<sup>15</sup> See, e.g., *Craftwood II, Inc. v. Tomy Int'l, Inc.*, No. SA CV 12-1710 DOC (ANx), 2013 WL 3756485, at \*4 (C.D. Cal. July 15, 2013) (noting that “the five-Justice majority in *Genesis* does attack some of the logic of the precedent on which *Pitt* relies”); *Chen v. Allstate Ins. Co.*, No. C 13-0685 PJH, 2013 WL 2558012, at \*9 (N.D. Cal. June 10, 2013) (noting that the *Genesis Healthcare* Court “did reject the reasoning that the Ninth Circuit in *Pitts* used . . . in the class action context” and that “while the Supreme Court might at some future date actually overrule *Pitts* and decisions from other Circuits holding that the rule articulated in *Genesis* also applies in class actions, as of now that has not happened . . .”), *appeal pending* (9th Cir. No. 13-16816); *Epstein*, 2014 WL 1133567, at \*11 & n.10 (noting that “there are reasons not to” find a defendant’s conduct in paying the class representative’s claim transitory, quoting *Genesis Healthcare*); ER 15 n.5.

Even assuming that *Pitts*’ “transitory” analysis might theoretically apply post-*Genesis Healthcare* and outside of the Rule 68 context, it still does not apply here. The district court considered and rejected the argument that NAC’s conduct was “tactical”; it did

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<sup>15</sup> In fact, the issue is pending before this Court in *Chen v. Allstate Ins. Co.*, No. 13-16816.

not fail to consider this evidence, as Appellants argue.<sup>16</sup> (AOB 5.) The court's order addressed both the timing of the refund and the assertion that Appellants had not asked for refunds. (ER 10:5-14, ER 16:17-17:3.)

The district court also had evidence of the unique circumstances of Amkraut's no-risk trial order of Super Beta Prostate, and the fact that Amkraut conveniently appeared in this action a very short time after he received his trial shipment and after NAC filed a motion challenging Luman's standing to sue. These questionable litigation tactics do not give Amkraut standing to sue.

Amkraut cannot meet his burden to demonstrate that the district court had jurisdiction over his claims.

**D. Both Appellants Lack Standing to Seek Injunctive Relief on Their Own Behalf or on Behalf of a Class.**

The district court also correctly held that it lacked jurisdiction over Appellants' claims for injunctive relief. Appellants did not and cannot allege that they will ever buy Super Beta Prostate again, because they contend that it is unsafe and ineffective. As Appellants'

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<sup>16</sup> Appellants present as a distinct "issue" for review the assertion that the district court's remarks noting the absence of evidence of NAC making refunds as part of a litigation strategy were error. (AOB 4.) This is not a separate issue, as it is an inherent part of the analysis showing why *Pitts* does not apply here.

counsel stated at the hearing, “I have a hard time imagining that these plaintiffs would purchase the product.” (SER 8:12-13.)

However, a plaintiff seeking an injunction in federal court must show that there is a “real and immediate threat” that he is “likely to suffer future injury” from the defendant’s conduct. *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983); *Ervine v. Desert View Reg’l Med. Ctr. Holdings, LLC*, 753 F.3d 862, 868 (9th Cir. 2014) (“it is not the presence or ‘absence of a past injury’ that determines Article III standing to seek injunctive relief; it is the imminent ‘prospect of future injury’”) (citation omitted); *Rivas v. Rail Delivery Service, Inc.*, 423 F.3d 1079, 1082-83 (9th Cir. 2005) (plaintiffs could not sue for an injunction where they conceded the violations caused them no injury, even though the statute provided for an injunction in the absence of injury); *Cantrell*, 241 F.3d at 683 (California statute that granted broad standing for taxpayers to sue for injunctive relief was not sufficient to confer Article III standing on uninjured plaintiffs).

Further, “system-wide injunctive relief is not available based on alleged injuries to unnamed members of a proposed class. . . . Unless the named plaintiffs are themselves entitled to seek injunctive relief,

they may not represent a class seeking that relief.” *Hodgers-Durgin v. de la Vina*, 199 F.3d 1037, 1045 (9th Cir. 1999).

Many cases apply this principle in false advertising cases, where the plaintiff complains that he was misled into purchasing a product that did not meet his expectations. *See, e.g., Rahman*, 2014 WL 325241, at \*10 (plaintiff lacked standing to seek injunctive relief in false advertising case where he did not allege that he intended to purchase the product again in the future).

In *Delarosa*, 2012 WL 8716658, the plaintiff sued for fraud and violation of consumer protection statutes, alleging that the defendant’s advertising was false and that its cold remedy did not work. The court ruled that the plaintiff could not meet Article III requirements for standing to seek an injunction: “Because Plaintiff does not believe the product works and does not intend to purchase it again, there is not a ‘sufficient likelihood that [she] will again be wronged in a similar way.’ Thus, she does not have Article III standing to seek injunctive relief because there is no ‘threat of future injury’ that could be redressed by injunctive relief.” *Id.* at \*4 (quoting *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 979 (9th Cir. 2011), and *Bates v. United Parcel Serv.*, 511 F.3d 974, 985 (9th Cir. 2007)); *see also*

*Mason*, 2013 WL 1969957, at \*2 (plaintiff lacked Article III standing to pursue claims for injunctive relief because, as she asserted the product did not work, there was no likelihood that she would purchase the product again).<sup>17</sup>

As the district court here noted (ER 18:21-19:7), several courts within this Circuit have found plaintiffs have standing to pursue claims for injunctive relief for violation of California consumer statutes, even absent any actual or threatened injury to the named plaintiffs. *See, e.g., Henderson v. Gruma Corp.*, No. CV 10-04173 AHM (AJWx), 2011 WL 1362188, at \*7 (C.D. Cal. Apr. 11, 2011) (“If the Court were to construe Article III standing for [California] FAL and UCL claims as narrowly as the Defendant advocates, federal

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<sup>17</sup> *See also McNair v. Synapse Group, Inc.*, 672 F.3d 213, 224-25 (3d Cir. 2012) (plaintiffs who did not intend to buy product because of past misrepresentations do not have standing to seek injunctive relief, on their own behalf or on behalf of a class); *Campion v. Old Republic Home Protection Co.*, 861 F. Supp. 2d 1139, 1149-50 (S.D. Cal. 2012) (where a plaintiff has knowledge of defendant’s alleged misconduct, the “Plaintiff cannot show he is realistically threatened by a repetition of the alleged violation”); *Laster v. T-Mobile USA, Inc.*, No. 05cv1167, 2009 WL 4842801, \*4 (S.D. Cal. Dec. 14, 2009) (plaintiffs’ knowledge of defendant’s misconduct “precludes them from showing likelihood of future injury”), *vacated in part on other grounds*, 466 Fed. Appx. 613 (9th Cir. 2012); *Cattie v. Wal-Mart Stores, Inc.*, 504 F. Supp. 2d 939, 951 (S.D. Cal. 2007) (“[I]t is unclear how prospective relief will redress [plaintiff’s] injury since she is now fully aware of [the alleged false advertising].”).

courts would be precluded from enjoining false advertising under California consumer protection laws because a plaintiff who had been injured would always be deemed to avoid the case of the injury thereafter . . . and would never have Article III standing.”); *Lanovaz v. Twinings N. Am., Inc.*, No. C-12-02646-RMW, 2014 WL 46822, at \*10 (N.D. Cal. Jan. 6, 2014) (same). But Article III does not allow such a flexible approach: “[A]s important as consumer protection is, it is not within the Court’s authority to carve out an exception to Article III’s standing requirements to further the purpose of California’s consumer protection laws.” *Mason*, 2013 WL 1969957, at \*5<sup>18</sup>; see also *Delarosa*, 2012 WL 8716658, at \*5 (“[t]o the extent that *Henderson* and other cases purport to create a public-policy exemption to the standing requirement, that exception does not square with Article III’s mandate”); *Burns*, 2014 WL 3728115, at \*3 (same).<sup>19</sup>

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<sup>18</sup> The *Mason* court also observed that, despite any suggestion in *Meyer*, 45 Cal. 4th at 646, that a plaintiff might be able to seek to enjoin business practices on behalf of the public even if the plaintiff was not likely to suffer future harm, “as a *federal* court, this Court must make sure that the threshold requirements imposed by Article III are satisfied.” *Mason*, 2013 WL 1969957, at \*3 n.1 (emphasis in original).

<sup>19</sup> Precluding plaintiffs from seeking injunctive relief in federal court because they lack Article III standing does not mean that consumer



The district court properly considered all of the relevant evidence, and concluded that it lacked jurisdiction over any of the claims asserted in this lawsuit. That decision was correct and should be affirmed.

**V. THE COMPLAINT FAILED TO STATE ANY VIABLE CLAIM AND WAS SUBJECT TO DISMISSAL UNDER RULE 12(B)(6).**

In the event that this Court concludes that Appellants had standing and that the claims were not moot, the judgment may be affirmed on the independent ground that Appellants' core legal theory was nonactionable. The fundamental factual predicate of Appellants' case – that the active ingredient in Super Beta Prostate was ineffective in treating BPH – was demonstrably false, as shown by the very scientific study that Appellants alleged proved their claim.

As noted, Appellants alleged that representations that Super Beta Prostate was effective to treat BPH (as discussed, NAC ads did not say this) were false because of a 1995 study published in *The Lancet* that stated:

The effect of phytopharmaceuticals on BPH is controversial because no clear mechanisms of action

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protection laws go unenforced, as such relief may be sought in state court. *Mason*, 2013 WL 1969957, at \*5; *Delarosa*, 2012 WL 8716658, at \*2.

have been established, and their effect has been attributed to placebo responses. . . . Since other forms of medical treatment of BPH have been shown to be effective, it is questionable whether phytopharmaceutical drugs should continue to be prescribed.

(ER 171 ¶ 1; AOB 8.)<sup>20</sup> On its face, this statement does not show falsity – only, at most, equivocal results on efficacy.

But the district court wisely ordered Appellants to submit a copy of the actual study on which the complaint relied. (Dkt. No. 30.) The study itself destroys Appellants’ theory that Super Beta Prostate is ineffective. The study says exactly the opposite: “*Significant improvement in symptoms and urinary flow parameters show the effectiveness of beta-sitosterol in the treatment of benign prostatic hyperplasia.*” (SER 16 (emphasis added).) The study also says “[t]he results [of the study] show a *significant effect of beta-sitosterol in patients with symptomatic BPH on symptoms* . . . . Objective parameters of urine flow were also improved more than in the placebo group.” (SER 19 (emphasis added).) Thus, the foundational factual allegation of Appellants’ entire lawsuit is demonstrably false. They have no other factual basis to support their theory of false advertising.

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<sup>20</sup> *The Lancet* study was not conducted on Super Beta Prostate, but rather on a drug known as “Harzol.” (ER 171 ¶ 1.)

Without the factual predicate of *The Lancet* study as supposed evidence of falsity, Appellants' case rested on the theory that there is *no substantiation* for NAC's advertising claims. That theory is not actionable under California law.

Under California law, a false advertising plaintiff must plead and prove that the advertising is false. *Arizona Cartridge Remanufacturers Ass'n v. Lexmark Int'l*, 421 F.3d 981, 985 (9th Cir. 2005) (under California law, "[t]he plaintiff has the burden of proving that the challenged advertising is false or misleading to a reasonable consumer"); *Stanley v. Bayer Healthcare LLC*, No. 11cv862-IEG (BCM), 2012 WL 1132920, at \*3 (S.D.Cal. April 3, 2012); *Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727-LAB-MDD, 2012 WL 5382218, at \*1 (S.D.Cal. Nov. 1, 2012). In contrast, false advertising claims by private parties based on the theory that there is no scientific basis for the advertised efficacy of a product are not actionable. *King Bio Pharmaceuticals*, 107 Cal. App. 4th at 1344 (affirming judgment for defendant homeopathic remedy manufacturer in action where plaintiff claimed defendant's products were "drugs," that there was no

scientific evidence supporting defendant's efficacy claims, and that defendant's products were not effective).<sup>21</sup>

There is a significant difference between saying there is no proof for advertising claims (which is not cognizable), and saying that there is scientific evidence that actually *disproves* advertising claims. *See, e.g., In re Clorox Consumer Litigation*, 894 F. Supp. 2d 1224, 1233 (N.D. Cal. 2012) (acknowledging the critical difference between “alleging there is no competent scientific evidence to support [defendant's advertising] claims” and alleging that “competent scientific evidence shows that [defendant's] claims are objectively

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<sup>21</sup> California district courts have dismissed unfair competition, false advertising, CLRA, and breach of warranty claims based on the alleged lack of substantiation for the defendant's advertising. *See Fraker v. Bayer Corp.*, No. CV F 08-1564 AWI GSA, 2009 WL 5865687, at \*8-\*9 (E.D. Cal. Oct. 6, 2009) (California law provides “no private remedy for unsubstantiated advertising” and finding “no authority for the proposition that the absence of substantiation of an advertising claim is, itself, falsity or somehow misleading”); *Chavez v. Nestle USA, Inc.*, No. CV 09-9192-GW (CWx), 2011 WL 2150128, at \*5-6 (C.D. Cal. May 19, 2011) (“‘[l]ack of substantiation’ is not a cognizable theory under the UCL or FAL”), *aff'd in part & rev'd in part*, 511 Fed. Appx. 606 (9th Cir. 2013); *Barrera v. Pharmavite, LLC*, No. CV 2:11-04153 (C.D. Cal. Sept. 19, 2011) (unpublished minute order at SER 39) (notwithstanding “conclusor[y]” allegations that the label representations were “false and misleading” and “factually baseless,” plaintiff was in fact alleging a “lack of substantiation” theory that failed as a matter of law); *Stanley*, 2012 WL 1132920 at \*4, 8-10 (“alleged lack of substantiation does not render claims false and misleading under the UCL or CLRA”).

false”); *Eckler*, 2012 WL 5382218, \*3 (“There is a difference, intuitively, between a claim that has no evidentiary support one way or the other and a claim that’s actually been disproved”). Appellants tried to use *The Lancet* study to state the former type of claim – one based on scientific evidence that proves falsity.

Similarly, a claim that a defendant lacks support for general efficacy claims is not actionable. *Cook, Perkiss & Liehe, Inc. v. Northern Cal. Collection Serv., Inc.*, 911 F.2d 242, 245-46 (9th Cir. 1990); *Autodesk, Inc. v. Dassault Sys. Solidworks Corp.*, 685 F. Supp. 2d 1001, 1019 (N.D.Cal. 2009) (dismissing false advertising claim where “the heart [of the representation] is effectiveness, a highly subjective standard . . . . Such a claim is a vague and unmeasurable claim of superiority that constitutes non-actionable puffery.”); *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, No. MDL 08-1934 PSG (AGRx), 2009 WL 1703285, at \*6 (C.D.Cal. June 17, 2009) (allegations that drug was effective for certain purposes not actionable as a fraud claim), *aff’d*, 400 Fed. Appx. 255 (9th Cir. 2010).

In other words, it was Appellants' burden to allege, and then prove, facts that *disproved* NAC's advertising claims and thus established those claims as false. They did not do so.

Instead, Appellants alleged that the advertising claims for Super Beta Prostate are not supported by competent scientific evidence. For example, Appellants alleged that Super Beta Prostate is "not generally recognized among experts . . . as safe and effective for use . . ." (ER 173 ¶ 5); that claims allegedly suggesting that Super Beta Prostate treats symptoms of BPH "have not been authorized by the FDA or any scientific body" (ER 191 ¶¶ 56-57); and that Super Beta Prostate was "unfit for [its] intended and ordinary purpose because there is no competent and reliable scientific evidence that Super Beta Prostate is a safe and effective treatment for the symptoms of BPH." (ER 194 ¶ 83.) These are clear allegations that NAC's advertising is false merely because of an alleged lack of substantiation.

Appellants alleged and argued that three facts purportedly demonstrated that NAC's advertising was false. (ER 9:21-26; SER 7:17-25; SER 11:18-22.) But none of these supposed facts has anything to do with whether or not the product works as advertised.

Appellants maintained that *The Lancet* study showed the ads were false. As discussed above, that is not what the study actually says. Appellants were unable to explain at oral argument how they could possibly have cited and relied on this study for the proposition that representations of effectiveness are false. Counsel could offer only that “the gist of [the article] is that it’s unclear what the effect is and that more – the ultimate conclusion is there needs to be more study of the effectiveness of beta-sitosterol on men with BPH. I think it’s at best questionable, I think it’s raising serious questions about the effectiveness of beta-sitosterol, and that is the upside. The authors of the study even recognize the limits of their study and indicate that. . . it was one study with a few patients over a very short period of time.” (SER 6:7-16.)<sup>22</sup>

So, having been called on the carpet for relying on a scientific study that refutes their underlying theory of the case, Appellants’ fall-

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<sup>22</sup> The actual language of *The Lancet* study, which could not be clearer, trumps Appellants’ attempt to spin an interpretation that supports their theory. See *Nishimatsu Const. Co., Ltd. v. Houston Nat’l Bank*, 515 F.2d 1200, 1206 (5th Cir. 1975) (language in document attached to the complaint controls over contradictory allegation); *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir.) (in ruling on Rule 12(b)(6) motion, court may consider document relied upon in complaint, although not attached), *cert. denied*, 525 U.S. 1001 (1998).

back position was to argue that the study instead shows a lack of substantiation. As the court noted, “I understand the 180-degree difference on this point.” (SER 7:15-16.) Appellants still cite this study in their AOB as evidence of falsity, without even mentioning the study’s actual conclusions or their concession at oral argument. (AOB 8.)

In addition to *The Lancet study*, Appellants relied on the supposed expert medical opinion of Jeffrey Zielinski. As alleged in the FAC, Zielinski is an actor who was hired to appear in a commercial for Super Beta Prostate. As Appellants alleged, he was given no information about the product, told to put on a white coat, and read from a teleprompter. (ER 171-172 ¶ 2.) While he allegedly was a former doctor, he has not practiced medicine since 2009. (*Id.*) The FAC points to NAC’s use of a non-doctor actor in a commercial as evidence of fraud.

Thus, it is supremely ironic that Appellants also tout Zielinski as an expert on the non-effectiveness of Super Beta Prostate. Although Zielinski established, with Appellants’ help, that he knows nothing at all about the product, they quote him as saying:

*If I were a practicing physician, I would not recommend Super Beta Prostate for the treatment of BPH or its*



symptoms. . . . I would not recommend Super Beta Prostate to anyone for any purpose. I believe it is unsuitable for the treatment of BPH, and possibly unsafe because it is a formulation that has never been studied and it includes mixed sterols in very high doses that could cause significant adverse events.

(ER 172-73 ¶ 2 (underlining in original; italics added).) Zielinski's alleged opinions are not allegations of fact that the Court must accept as true. *See Koehler v. Litehouse, Inc.*, No. CV 12-04055 SI, 2012 WL 6217635 at \*3 (N.D. Cal. Dec. 13, 2012) (granting motion to strike statements of plaintiff's expert witness included in the complaint, holding that such opinions did not amount to statements of fact).

In any event, as Appellants concede, Zielinski "knew nothing about the product." (AOB 7-8.) Thus, his alleged expert actor/doctor opinions do not support the contention that the ads are false.

Appellants' third item of supposed evidence that the statements about Super Beta Prostate are false is the assertion that the person who developed Super Beta Prostate is not a medical professional and was convicted of certain unrelated crimes. (ER 184-85 ¶¶ 35-37; AOB 7.) Obviously, this is nothing more than inflammatory innuendo and does not demonstrate – or have anything to do with – whether Super Beta Prostate does or does not produce any of the desired effects.

After the hearing on the motions to dismiss, Appellants submitted to the district court a belated request for judicial notice of an FDA regulation, 21 C.F.R. § 310.532, that purportedly applies to over-the-counter products that claim to relieve BPH symptoms. (ER 21.) That regulation, which was adopted in 1990, five years before the publication of *The Lancet* study and 23 years before Appellants' untimely request for judicial notice, states that there "is a lack of adequate data to establish general recognition of the safety and effectiveness of [the 'amino acids glycine, alanine, and glutamic acid' and 'the ingredient sabal'] or any other ingredients for OTC [over-the-counter] use in relieving the symptoms of benign prostatic hypertrophy" and that "any OTC drug product containing ingredients offered for use in relieving the symptoms of benign prostatic hypertrophy cannot be generally recognized as safe and effective." 21 C.F.R. § 310.532(a). To the extent Appellants attempt to rely on this regulation, it is not evidence of an ineffective product; rather, it confirms that Appellants' claims rest on a non-actionable lack of substantiation theory.

In summary, without *The Lancet* study, which contradicts their theory of the case, Appellants' entire case was based on a non-actionable theory that underlies every one of their claims.

## **VI. CONCLUSION**

There was never a factual or legal basis for this lawsuit. Appellants relied on *The Lancet* study as the primary basis for their claim that Super Beta Prostate was not effective in treating BPH. But *The Lancet* study actually refutes that essential factual allegation. Without that, Appellants have no case. The district court was correct in concluding that Appellants lack standing to bring their case, which does not state a viable claim for relief in any event. The district court's judgment of dismissal should be affirmed.

Dated: August 26, 2014

MANATT, PHELPS & PHILLIPS, LLP

By: /s/ Brad W. Seiling

Brad W. Seiling

*Attorneys for Appellee*

NAC MARKETING COMPANY, LLC

### STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, Appellee states that it is not aware of any related cases pending in this Court.

CERTIFICATE OF COMPLIANCE PURSUANT TO  
CIRCUIT RULE 32-1

Pursuant to Circuit Rule 32-1, I certify that this Appellee's Brief is proportionately spaced, has a typeface of 14 points or more and contains 9,364 words, excluding the Corporate Disclosure Statement, table of contents, table of authorities, the caption page, Statement of Related Cases and this certification page.

Dated: August 26, 2014

MANATT, PHELPS & PHILLIPS, LLP

By: /s/ Brad W. Seiling

Brad W. Seiling

*Attorneys for Appellee*

NAC MARKETING COMPANY, LLC

**CERTIFICATE OF SERVICE**  
**When All Case Participants are Registered for the**  
**Appellate CM/ECF System**

I hereby certify that on August 26, 2014, I electronically filed the foregoing **BRIEF OF APPELLEE NAC MARKETING COMPANY, LLC** with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Signature	s/Brigette Scoggins
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